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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,187	04/21/2000	Amy E. Baker	425802000200	7012

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EXAMINER
YU, GINA C

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n No. 09/557,187	Applicant(s) BAKER, AMY E.	
	Examiner Gina C. Yu	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P ri d f r R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of Amendment filed on November 20, 2001. Claims 1-11 and 13-20 are pending. The claim rejections under 35 U.S.C. § 102 made over Biedermann and O'Halloran are withdrawn in view of the amendment by applicants. The claim rejections under § 103 made over Biedermann in view of Sciarra and Biedermann in view of Guang Lin are also withdrawn in view of the claim amendment.

Applicant is requested to note that in claims 1 and 11, the term "fine mist pump spray" is unclear because it appears that "fine mist spray" and "pump spray" are distict apparatus. The confusion arises from the applicants' disclosure on specification p. 3, lines 17- 19 and p. 3, line 31 – p. 4, line 8. There, applicants state that the terms "aerosols" and "fine mist spray" are used interchangeably, wherein the instant claims the term "fine mist" is used to describe pump spray which is supposed to be distinctive from aerosol. It is not clear, therefore, based on applicants' own disclosure, what the claimed subject matter is.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "fine mist pump spray pump dispenser" in claim 11. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 6-11, 13, 16-18, and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone (US 4322020) in view of Biedermann et al. (US 6150403) ("Biedermann").

Stone teaches an invertible pump sprayer which is said to overcome the disadvantageous of conventional aerosols in cosmetics and pharmaceutical applications. See col. 1, line 9 – col. 2, line 65. The reference teaches that pump sprays are preferred over aerosols because of the clogging problem in the aerosol valves and environmental concerns. See col. 1, lines 22-35. In Example 1, the reference describes a topical anesthetic solution spray having an average particle size of approximately 200 microns when the viscosity of the solution is 38 cps. at 20 °C.

While the particle size does not expressly meet the limitation of instant claim 2, the reference teaches that "the particle size of the spray will vary with the rheology of the liquid being sprayed as well as with the orifice size." See col. 5, lines 44 – 49. It is further disclosed that "the lower the viscosity of the liquid and the smaller the orifice size, the smaller the particle size obtained." Thus it would have been obvious to a routineer to expect that a lower particle size would have been produced from a less viscous solution. Stone lacks the teaching of anti-acne composition containing salicylic acid.

Biedermann et al. describe topical compositions for reducing oily appearance on skin, which comprise anti-acne agents. The reference teaches that the composition may comprise 0.05 – 10% of the anti-acne agents, wherein the anti-acne agents may be salicylic acid. See col. 8, lines 13 – 50. The reference further teaches that the composition may comprise a dermatologically acceptable carrier in the form of sprays and aerosols, wherein the carriers may be alcohol and water. See col. 12, line 19 – col. 13, line 19. Ethanol is disclosed in col. 12, lines 59 – col. 13, line 2. The formulation in Example 10 uses denatured ethanol. See instant claim 9. The reference also teaches that the combination of cetyl betaine and salicylic acid is preferred. See instant claim 6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the topical anesthetic solution in Stone with the anti-acne composition comprising salicylic acid as suggested by Biedermann because of the expectation of successfully producing a topical anti-acne pump spray.

2. Claims 3-5, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone and Biedermann as applied to claims 1, 2, 6-11, and 16-20 above, or alternatively, further in view of Guang Lin et al. (US 5612324) ("Guang Lin").

Stone and Biedermann are discussed above. Biedermann teaches that the most preferred pH of the composition ranges from 4 to 7 and from 4.5 to 5.5. See col. 24, lines 62 – 67.

Guang Lin teaches methods for treating acne with salicylic acid and pantothenic acid or its derivative. The composition in the reference comprise 0.01 – 20% by weight of salicylic acid, dexpanthenol, and a carrier, wherein the preferred carrier is a mixture

of 20-50% of ethanol, isopropanol or mixtures thereof, and 50-80% of water. See col. 2, lines 45 – 56; col. 5, lines 55 – 67; instant claims 7 and 8. As an acceptable carrier of the invention, spray and aerosol are mentioned. See col. 4, lines 19 – 38. The reference also teaches that the pH range for the composition should be such that the ionization of the salicylic acid is suppressed while the solution readily penetrates the skin. See col. 3, line 54 – col. 4, line 18. The preferred pH range for the composition is 2 to 7. See col. 4, lines 13 – 17.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the spray composition of the combined references by adjusting the pH of the solution within the disclosed range in Guang Lin because of the expectation to have produced the salicylic acid solution with suppressed ionization and enhanced penetration.

3. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone and Biedermann as applied to claim 1, 2, 6-11, 13-18, and 20 above, or, alternatively, further in view of Sciarra (Remington: Practice of Science and Pharmacy, 19th Ed., p. 1776 – 1692.).

Stone also lacks the explicit teaching of the volume of the solution per actuation. Given, however, the teaching of the topical and pharmaceutical use of Stone's spray dispenser, it is presumed that the actuation dosage of the pump spray in Stone would be within the obvious range of the claimed invention. The burden is shifted to applicants to show how, if any, the instant invention is patently distinct from the prior art.

Sciarra teaches that topical aerosols have been used for preparations for the treatment of acne. See p. 1676, 1st par. He also teaches that for topical sprays particles are produced in size from 50-200 μm, which meets claim 2. See p. 1677, 4th par. It is further disclosed that for a typical metered-dose aerosol delivery system for pharmaceuticals, the size of the chamber can be modified so that about 25-150 μL of the solution can be delivered per actuation, which meets claim 19. See p. 1688, 6th par. – p. 1689, 1st par.

Given the general teaching of topical anti-acne pump spray in the combined references, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have looked to the prior art such as Sciarra for suitable dosage of the pharmaceutical. It is obvious that the routineer would have found a motivation to modify the pump spray in the combined references by designing the chamber size as taught by Sciarra to adjust the delivered amount per acutation as desired.

4. Claims 1, 2, 6-11, 16-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al. (US 6050457) (Arnold) in view of O'Halloran et al. (US 6168798 B1) ("O'Halloran").

Arnold teaches a high pressure manually-actuated spray pump for various applications, including cosmetics, perfume, deodorants, etc. See abstract; col. 12, lines 18-25. The non-aerosol spray pump in the invention is said to generate ultra fine sprays, which the reference defines as sprays having mean particle sizes of about 40 microns. See col. 1, lines 5 – 25.

Arnold lacks the teaching of anti-acne spray composition.

O'Halloran et al. describe non-irritating compositions for treating acne and related skin disorders, containing 0.1-15% by weight of ketatolytic compound, 5-55% of alcohol, and 50-90% of water. See col. 2, line 23 – col. 3, line 27. See also claims. The reference teaches that the composition may be used in the form of aerosol sprays. See col. 6, lines 1 – 8. Example 1 illustrates the formulation for a non-irritating cosmetic astringent, comprising 30% by weight of denatured alcohol, 66.14% of water, and 0.52% of salicylic acid. See col. 8, lines 33 – 48. The reference teaches that the composition is nongreasy, leaves no residue upon application, and dries quickly. See col. 7, line 61 – col. 8, line7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the topical anesthetic solution in Stone with the anti-acne composition comprising salicylic acid as suggested by O'Halloran because of the expectation of successfully producing a topical anti-acne pump spray.

5. Claims 11 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Biedermann et al. in view of Rhea (U.S. Pat. No. 5,195,664).

Biedermann et al. is discussed above. While the reference teaches the composition may be in dispensed using spray or aerosol, it fails to teach the spray container as described in claim 13.

Rhea discloses all directional fluid pick up for spray containers, which meets claim 13. See col. 2, line 63 – col. 3, line 55; col. 4, line 14 – col. 7, line 43.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the spray in Biedermann et al. by employing the

dispensing system in Rhea because of the expectation to have produced a topical spray that may be used from all positions, as suggested by Rhea.

Response to Arguments

Applicant's arguments with respect to claim rejections on claims 1-20 have been considered but are moot in view of the new ground(s) of rejection in part and unpersuasive in part.

Applicants' remarks regarding the § 102 rejections based on Biedermann and O'Halloran are moot in view of the amended scope of the claims by applicants.

Applicants' argument regarding the § 103 rejections over Biedermann in view of Guang Lin and Bidermann in view of Sciarra are moot in view of the amended scope of the claims by applicants.

Applicants' argument regarding § 103 rejection over Biedermann in view of Rhea is not persuasive. Given The fact that Rhea is silent about using its dispenser for cosmetic solutions does not necessarily negate the obviousness because the reference teaches that the spray dispenser is use for many purposes. Examiner maintains the position that the two references are combinable because, while Biedermann is directed to cosmetic composition which can be dispensed by spray, Rhea teaches fluid handling devices and special dispensing devices. Applicants' argument that the prior arts are not combinable because Biermann teaches aerosol containing propellants while Rhea teaches pump spray cannot be taken as persuasive because the instant claims are confusing as to how applicants define "aerosol" and "fine mist spray", as explained in this office action p. 2, second paragraph.

Applicants argue that Guang Lin does not teach sprays or fine mist spray and instead describe liquid "dab-on" applicators. In response, examiner notes that that while Guang Lin's invention is directed to dab-on applicators, the reference nevertheless teaches the applicability of the composition by spray dispensers as well, as discussed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezi can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
February 9, 2002

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